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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/569,234	01/29/2007	Lindsey Jane Hudson	1300-1-014PCT/US	7475
23565	7590	07/16/2008		
KLAUBER & JACKSON 411 HACKENSACK AVENUE HACKENSACK, NJ 07601			EXAMINER GUSSOW, ANNE	
			ART UNIT 1643	PAPER NUMBER
			MAIL DATE 07/16/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/569,234	HUDSON, LINDSEY JANE	
	Examiner	Art Unit	
	ANNE M. GUSSOW	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-26 is/are pending in the application.
- 4a) Of the above claim(s) 7-18 and 24-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 February 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/12/06</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Sequence alignments</u> . |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group VI, claims 19-23, in the reply filed on May 12, 2008 is acknowledged. The traversal is on the ground(s) that the groups designated by the examiner fail to define compositions and methods with properties so distinct as to warrant separate Examination and Search. The Examiner's assertions to the contrary notwithstanding, Applicants respectfully submit that conjoint examination and inclusion of all of the claims of the present application would not present an undue burden on the Examiner (see response page 3). This is not found persuasive because the claims lack unity of invention based on the teachings of de Marco in view of Kennedy. The claims are not so linked as to form a single general concept under PCT Rule 13.1 because they lack a special technical feature.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 7-18 and 24-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 12, 2008.

3. Claims 19-23 are under examination.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on June 12, 2006 has been fully considered by the examiner and an initialed copy of the IDS is included with the mailing of this Office Action.

Drawings

5. The drawings are objected to because Figure 1 contains an unidentified sequence under the phrase "Figure 1". It is believed that this sequence is a part of Figure 2a. Correction to either label the unidentified sequence or include the sequence on the same page as the rest of Figure 2a is necessary. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and

informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

6. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Detection of MAL2 protein in carcinoma diagnosis.

7. The use of the trademark Herceptin® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The trademark symbol and generic terminology have not been included for Herceptin®. Appropriate correction is required.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 19-23 are rejected under 35 U.S.C. 102(a, e) as being anticipated by Monahan, et al. (US PG PUB 2003/0087250, published May 8, 2003, filed March 14, 2002).

The claims recite a method of screening for and/or diagnosis or prognosis of carcinoma in a subject, and/or monitoring the effectiveness of carcinoma therapy, which comprises the step of detecting and/or quantifying in a biological sample obtained from said subject, the expression of a MAL2 polypeptide, wherein the expression of said polypeptide is compared to a previously determined reference range or control, wherein the step of detecting comprises: (a) contacting the sample with a capture reagent that is specific for a MAL2 polypeptide; and (b) detecting whether binding has occurred between the capture reagent and said polypeptide in the sample, wherein step (b) comprises detecting the captured polypeptide using a directly or indirectly labeled detection reagent, wherein the capture reagent is immobilised on a solid phase.

Monahan, et al. teach a diagnostic method of assessing whether a patient has ovarian cancer or is at risk for developing ovarian cancer by comparing the level of expression of a marker in a sample to the level of the marker in a control sample

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(paragraph 15). Monahan, et al. teach the sample may be an ovarian tissue biopsy, histology section, blood fluid, lymph, ascites fluid, gynecological fluid, cystic fluid, urine, or fluids collected by peritoneal rinsing (paragraph 54). Monahan, et al. teach a marker of the invention as M472, secreted protein HETKL27 which is identical to MAL2 (see sequence alignment). Monahan, et al. teach the marker may be detected by an antibody which may be coupled to a detectable substance (paragraph 208) and immobilized on a solid support (paragraph 284). Since the claims do not define the specific carcinoma or the specific biological sample of the method and Monahan, et al. teach detecting the identical protein to MAL2 in a sample for detection of ovarian cancer, all the limitations of the claims have been met.

10. Claims 19-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Ruben, et al. (WO 01/36440 A1, published May 25, 2001, as cited on the IDS).

The claims have been described supra.

Ruben, et al. teach a MAL-a protein which is identical to the instant MAL2 polypeptide (see sequence alignment) and has elevated expression in a number of adenocarcinomas (page 20). Ruben, et al. teach antibodies that recognize MAL-a for diagnosis of tumors, particularly cancers of the ovary, colon, lung and prostate, by comparing the expression of MAL-a in a tissue or bodily fluid to the expression level in a healthy tissue or bodily fluid (page 29). Ruben, et al. teach the antibody may be bound to a solid support (page 30) and labeled for detection (page 158). Since the claims do not define the specific carcinoma or the specific biological sample of the method and

Ruben, et al. teach detecting the identical protein to MAL-2 in a sample for detection of adenocarcinoma including ovary, colon, lung, and prostate, all the limitations of the claims have been met.

Conclusion

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is (571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

July 2, 2008

/Larry R. Helms/
Supervisory Patent Examiner, Art Unit 1643